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| S. No. | Brief Description of the deviation | Deviation category  \*(choose from list below) | Date  dd/mm/yyyy | | Corrective action if taken describe briefly | Date reported to ERB if applicable  dd/mm/yyyy | Patient continuation in trial after deviation identified  1 yes  2 No | PI initials |
| deviation occurred | investigators became aware of deviation |
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**Deviation category**

1. Consent document and process
2. Screening
3. Interventions
4. Randomization
5. Visit schedules /follow up
6. Investigational product IP management
7. Data management and Safety Reporting
8. Others specify \_\_\_\_\_\_\_\_\_\_\_

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| --- | --- | --- | --- |
| **Consent** | **Screening** | **Interventions** | **Randomization** |
| * Most recent ERB-approved consent document not used * Consent not obtained before initiating study procedures * consent document not appropriately signed/dates missing * Wrong version of consent form used * consent taken by unauthorized person (not on delegation of authority log * others specify \_\_\_\_\_\_\_\_\_ | * Inclusion criteria not met but participant was enrolled * Patient fall in any other exclusion criteria but was enrolled * Screening Performa incomplete unsigned or unstamped * Required eligibility labs or assessments were missed before enrollment * Others specify \_\_\_\_\_\_\_\_\_ | * Wrong treatment given (not per allocation/randomization) * Wrong intervention performed * Missed dose of investigational product * Study intervention not followed as per protocol schedule * Required procedures/labs/interventions missed. * Others specify \_\_\_\_\_\_\_\_\_\_\_ | * Randomization performed before informed consent * Participant randomized despite failing eligibility criteria * Incorrect randomization code used * Allocation envelope opened out of sequence * Wrong participant ID entered into randomization system * Randomization performed outside the permitted time window * Others specify \_\_\_\_\_\_\_\_\_\_ |
| **Visit schedules / follow up** | **Investigational product IP management** | **data management and Safety Reporting** | **Others** |
| * Participants missed scheduled visit * Visit conducted outside protocol-defined time window * Unscheduled visits not documented in the protocol * Visits specific tasks / procedures / labs not performed * Others specify \_\_\_\_\_\_\_\_\_ | * Incorrect storage temperature or conditions * IP dispensed without proper documentation * IP accountability records incomplete or inaccurate * Others specify \_\_\_\_\_\_\_\_\_ | * Case Report Form (CRF) incomplete or inconsistent with source documents * Source documents missing or not updated in real time * Data entry errors identified after monitoring * Adverse event not reported within required timeline * Serious adverse event (SAE) form incomplete or missing * Missing documentation for safety follow-up assessments * Others specify \_\_\_\_\_\_\_\_\_\_\_\_ | Specify \_\_\_\_\_\_\_\_\_\_\_ |